

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re App	olication of: Jin-An Jiao et al.)		
Applicati	ion No: 10/618,338)	Art Unit:	1646
Filed:	July 11, 2003)	Confirmati	on No.: 8452
For:	ANTIBODIES FOR INHIBITING BLOOD COAGULATION AND METHODS OF USE THEREOF)))	Examiner:	Not yet known

CERTIFICATE OF MAILING/TRANSMISSION

I hereby certify that the correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 17, 2006.

Katelyn Nelson

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION-DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97 (b)(3)

Applicants hereby bring to the Examiner's attention the references listed on the accompanying form PTO-1449 in compliance with the requirements of 37 C.F.R. § § 1.56 and 1.97(b)(3). Pursuant to 37 C.F.R. § 1.98 (2)(i), Applicants have not enclosed copies of the cited U.S. patents or publications. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed publication dates should not be construed that the information in the cited documents was actually published or otherwise publicly available on the date indicated.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that each or all of the listed documents are material or constitute "prior art." Further, if the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Moreover, the Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, the Commissioner is authorized to charge any deficiencies or credit any overpayment to our **Deposit Account**, No. 06-1448, **Reference** TNA-005.04.

Respectfully submitted,

Date: January 17, 2006 Customer No: 25181

Patent Group Foley Hoag, LLP 155 Seaport Blvd. Boston, MA 02210-2600 Charlene A, Stern-Dombal, Reg. No. 57,961

Agent for Applicants Tel. No. (617) 832-1738 Fax. No. (617) 832-7000

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Form PTO-1449 INFORMA	TION I	DISCLOSURE CITA	TION		Number (Optional) -005.04	OILE	\sum_{i}	Applicat 10/61	tion Number 8.338		
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<u>-</u> -	ВТ	2003/0109680	06/12/	03	Jiao et	al.					_
	BU	2003/0082636	09/18/	03	Wong e	et al.					
	BV	2004/0229282	11/18/	04	Wong 6	et al.					
	вw	2005/0089929	04/28/	05	Jiao et	al.					
	вх	5,589,173	12/31/	96	O'Brien	et al.				· · · · · · · · · · · · · · · · · · ·	
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		OTH	ER DO	CUME	NTS		(Including	a Author	Title, Date, Pert	inant Pagas Ft	c)
		Albrecht et al., "A				monoclona					L.)
	BX	Fibrinolysis, 3:26	3-270 (1992)	·				J		
	BY	Almus et al., "Properties of Factor VIIa/Tissue Factor Complexes in an Umbilical Vein Model," Blood, 76(2):354-360 (1990)									
	BZ	Ardaillou et al., "C thrombin generat						nesis ir	human plat	telets via	-
		Barstad et al., "Pr	rocoagu	lant H	uman Monocyte	s Mediate T	issue Facto	r/Facto	or VIIa-Depe	ndent Plate	elet-
	CA	Thrombus Forma Thrombosis, and					aguiated Hu	ıman E	siood," Arteri	osierosis,	
	СВ	Beers et al., The Laboratories, pps			of Diagnosis ar	nd Therapy,	17 th edition,	, 1999,	Merck Rese	earch	
		Benedict et al., "N			tibody to Tissue	Factor Inhib	oits Intravas	cular 1	Thrombosis	without	
	СС	Imparing Extrava									
	Bjoern et al., "Human Plasma and Recombinant Factor VII," The Journal of Biological Chemistry, 266(17):11051-11057 (1991)										
	CE	Broze, George J., Jr., "Binding of Human Factor VII and VIIa to Monocytes," J. Clin. Invest., 70:526-535 (1982)									

Carson et al., "An Inhibitory Monoclonal Antibody Against Human Tissue Factor," Blood, 70(2):490-493 (1987)

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Form PTO-1449 INFORMATION DISCLOSURE CITATION		Docket Number (Optional) TNA-005.04	Application Number 10/618,338			
	APPLICATION	Applicant	10/018,338			
(Use seve	eral sheets if necessary)	Jin-An Jiao et al.				
		Filing Date July 11, 2003	Group Art Unit 1646			
	Carson et al "Monoclon		issue Factor, Which Block Interaction With Factor			
CG			issue Factor, Which block interaction with Factor			
			n by Recombinant Factor VIIa in Vivo Is Mediated			
СН		ournal of Clinical Investigation				
Ci	Normal Human Lung," A	m. Rev. Respir. Dis., 137(6):1				
C1	Prothrombinase Comple	x," The Journal of Biological C	Factor Xa Which Participate in the hemistry, 267(17):12323-12329 (1992)			
СК		oidermal growth factor domain ;" FEBS, 298(2,3):206-310 (19	of human coagulation factor VII is essential for 192)			
CL	((0.000)	bolytic agents and strategies,	Bailliere's Clinical Haematology, 8(2):425-435			
СМ			es on antibody-antigen interactions," Research in			
CN	Tumors Utilizing Monoclo Pathology, 145(6):1315-	Contrino et al., "In Situ Characterization of Antigenic and Functional Tissue Factor Expression in Human Tumors Utilizing Monoclonal Antibodies and Recombinant Factor VIIa as Probes," Americal Journal of Pathology, 145(6):1315-1322 (1994)				
со	Drake et al., "Functional Tissue Factor Is Entirely Cell Surface Expressed on Lipopolysaccharide- stimulated Human Blood Monocytes and a Constitutively Tissue Factor-producing Neoplastic Cell Line," The Journal of Cell Biology, 109:389-395 (1989)					
СР	Drake et al., "Selective Cellular Expression of Tissue Factor in Human Tissues," American Journal of Pathology, 134(5):1087-1097 (1989)					
cq	Fair et al., Cooperative Interaction Between Factor VII and Cell Surface-Expressed Tissue Factor, The Journal of Biological Chemistry, Vol. 262, August 25, 1987, pp. 11692-11698					
CR	Faulk et al., "Tissue Factor: Identification and Characterization of Cell Types in Human Placentae," Blood, 76(1):86-96 (1990)					
cs		or VIII: lessons from structure	o function," Blood Reviews, 19:15-17 (2005)			
СТ		stochemical detection of tissue nistry, 101:449-453 (1994)	factor (TF) on paraffin sections of routinely fixed			
CU	Immunologic Cross Read 158 (1975)	Gouault-Heilmann et al., "The Procoagulant Factor of Leukaemic Promyelocytes: Demonstration of Immunologic Cross Reactivity with Human Brain Tissue Factor," British Journal of Haematology, 30:151-158 (1975)				
CV		Grabowski et al., "The Functional Expression of Tissue Factor by Fibroblasts and Endothelial Cells Under Flow Conditions," Blood, 81(2):3265-3270 (1993)				
cw	Hamaguchi et al., "FDP D-Dimer Induces the Secretion of Interleukin-1, Urokinase-Type Plasminogen Activator, and Plasminogen Activator Inhibitor-2 in a Human Promonocytic Leukemia Cell Line," Blood, 77(1):94-100 (1991)					

orm PTO-1449 INFORMATION DISCLOSURE CITATION		Docket Number (Optional) TNA-005.04		Application Number		
IN AN APPLICATION		Applicant		10/618,338		
	ral sheets if necessary)	Jin-An Jiao et al.	<u> </u>			
		Filing Date		Group Art Unit		
	Haffman at al. "Human	July 11, 2003		1646		
сх	Factor: Implications for t 83(1):38-42 (1994)	the Therapeutic Mechanism	n of High-Dose Facto	tor VIIa, Independent of Tissue or VIIa in Hemophilia," Blood,		
СУ	the Crystal Structures of 894 (1998)	f Human Tissue Factor, Fab	b 5G9 and TF 5G9 C	Blood Coagulation Revealed by Complex," J. Mol. Biol., 275:873-		
CZ		Macrophage Tissue Factor n," Cellular Immunology, 15		t of the Delayed Hypersensitivity		
DA		ion of Functionally Importan , 114(5):691-696 (1993)	it Regions of Tissue	Factor by Using Monoclonal		
DB		of tissue factor activity redu sis," Biochemical Society Tr		ellular network formation in an in 17-221 (2002)		
DC	Jang et al., "Antithrombo Platelet-Mediated Arteria	otic Effect of a Monoclonal A al Thrombosis," Arterioscler	Antibody Against Tis osis and Thrombosi	ssue Factor in a Rabbit Model of is, 12(8):948-954 (1992)		
DD		Kirchhofer et al., "The Tissue Factor Region That Interacts with Factor Xa in the Activation of Factor VII," Biochemistry, 40:675-682 (2001)				
DE		Kumar et al., "Identification of Molecular Sites on Factor VII Which Mediate Its Assembly and Function in the Extrinsic Pathway Activation Complex," The Journal of Biological Chemistry, 266(2):915-921 (1991)				
DF	Kumar et al., "Specific m Biochem. 217:509-518 (n factor VII involved	in factor X activation," Eur. J.		
DG	by a Monoclonal Anti-tiss 93:114-120 (1994)					
DH	Maekawa et al., "Complement-Dependent Immunosuppressive Anti-Tissue Factor Monoclonal Antibody: The Establishment of Monoclonal Antibodies and Their Effect on Mixed Lymphocyte Reaction," Transplantation Proceedings, 25(4):2713-2715 (1993)					
DI	Martin et al., "Activation of Factor X by Factor VIIa on Monocyte Cell Surfaces," pp. 3828 – 3829 Blood. 1994 Jun 15;83(12):3828-9.					
DJ	Martin et al., "Tissue Factor: molecular recognition and cofactor function," The FASEB Journal, 9:852-859 (1995)					
DK	Masuda et al., "Association of tissue factor with a γ chain homodimer of the IgE receptor type I in cultured human monocytes," Eur. J. Immunol., 26:2529-2532 (1996)					
DL		McGee et al., "Functional Difference between Intrinsic and Extrinsic Coagulation Pathways," The Journal of Biological Chemistry, 266(13):8079-8085 (1991)				
DM	Merriam-Webster Online definition of thrombosis,	e dictionary, downloaded Oc 2 pages	tober 11, 2005, wor	ld wide web at m-w.com,		
DN	Morrissey et al., "Monoclonal Antibody Analysis of Purified and Cell-Associated Tissue Factor," Thrombosis Research, 52:247-261 (1988)					

Form PTO-1449		Docket Number (Optional)	Application Number	Sheet Fage 4 of 0			
INFORMATION DISCLOSURE CITATION		TNA-005.04	10/618,338				
	N APPLICATION	Applicant					
(Ose ser	veral sheets if necessary)	Jin-An Jiao et al. Filing Date	Group Art Unit				
		July 11, 2003	1646				
	Morrissey et al., "Resolu		imeric Forms of Tissue Factor, the	High-Affinity			
D		ctor VII," Thrombosis Research		,			
D		pression of Tissue Factor by Mo Acad. Sci. USA, December 1992	elanoma Cells Promotes Efficient l 2, Vol. 89, pp. 11832-11836	-lematogenous			
D	Muller et al., "Structure of Binding Site,"	of the Extracellular Domain of H	uman Tissue Factor: Location of th	ne Factor VIIa			
D			tion Model of the Tissue Factor Pachemistry, 25:4020-4033 (1986)	ithway of			
D		nan Endothelial Cells Following	ctional Expression of Tissue Factor Stimulation by Lipopolysaccharide				
D		ue Factor and Diisopropylfluoro	ation Factor VII and Tissue Factor: phosphate," Biochemical and Biop				
Di	Pawashe et al., "A Mono Stenotic Injured Rabbit C	oclonal Antibody Against Rabbit Carotid Arteries," Circulation Re	t Tissue Factor Inhibits Thrombus I search, January 1994, Vol. 74, No.	Formation in . 1, pp. 56-63			
D			gulation – Association of Factor VIIa al Chemistry, July 15, 1987, Vol. 20				
ים	w Price et al., "Tissue facto	or and tissue factor pathway inh	ibitor," Anaesthesia, 59:483-492 (2	<u>2</u> 004			
D.	x Tissue Factor Is Require	Rehemtulla et al., "The Integrity of the Cysteine 186-Cysteine 209 Bond of the Second Disulfide Loop of Tissue Factor Is Required for Binding of Factor VII," The Journal of Biological Chemistry, June 5, 1991, Vol. 266, No. 16, pp. 10294-10299					
D		Ruf et al., "An Anti-Tissue Factor Monoclonal Antibody Which Inhibits TF-VIIa Complex Is a Potent Anticoagulant in Plasma," Thrombosis and Haemostasis, 66(5):529-533 (1991)					
D.			s Two Different Exon-Encoded Re	gions in			
E/	A Affinity Calcium Binding	ion of Factor VII Association wit Sites in Factor VII Contribute to Vol. 266, August 25, 1991, pp. 1	th Tissue Factor in Solution – High Functionally Distinct Interactions," 15719-15725	and Low The Journal			
EI	Ruf et al., "Phospholipid- and Cofactor Function,"	Ruf et al., "Phospholipid-independent and –dependent Interactions Required for Tissue Factor Receptor and Cofactor Function," The Journal of Biological Chemistry, February 5, 1991, Vol. 266, pp. 2158-2166					
EC	Journal, April 1994, Vol.	Ruf et al., "Structural Biology of Tissue Factor, the Initiator of Thrombogenesis in Vivo," The FASEB Journal, April 1994, Vol. 8, pp. 385-390					
E	and Factor VII," The Jour 22210	rnal of Biological Chemistry, No	ed for Efficient Proteolytic Activation vember 5, 1992, Vol. 267, No. 31,	pp. 22206-			
E		he Tissue Factor Extracellular D Acad. Sci. USA, October 1991,	Domain Mediate the Recognition of Vol. 88, pp. 8430-8434	f the Ligand			

Sheet Page 5 of 6

Form PTO-1449			Docket Number (Optional)	Application Number	Sheet Fage 3 of 0
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)			TNA-005.04	10/618,338	
			Applicant Jin-An Jiao et al.		
(030	. SC PC/ (i	i succis ij necessiny)	Filing Date	Group Art Unit	
		/	July 11, 2003	1646	·
		Ryan et al., "Tumor Neci	rosis Factor-Induced Endothelial	Tissue Factor Is Associated With	5 4000
	EF	Vol. 80, No. 4, pp. 966-9		the Apical Surface," Blood, August 1	5, 1992,
				Human Bladder Carcinoma Cell Line	n (182) _
	EG			f Blooad Coagulation," The Journal of	
		Chemistry, Vol. 264, No.	17, June 15, 1989, pp. 9980-99	88	, Lietografi
		Salatti et al., "Modulation	of Procoagulant Activity of Extr	acellular Endothelial Matrix by Anti-T	issue
	ЕН			/al. Experiments with Flowing Non-	
				brinolysis, 1993, Vol. 4, pp. 881-890	
	EI			hibitor Sensitizes Rabbits to Endotor nan Reaction," Blood, September 15	
	EI	78, No. 6, pp. 1496-1502		ian Reaction, Blood, September 15	, 1991, VOI.
	-			and Associated Thrombi Is Mediated	Primarily by
	EJ	the Complex of Tissue F	actor and Factor VIIa, Pathophy	siology and Natural History," Corona	ry Artery
		Disease, January 1996,	Vol. 7, No. 1, pp. 57-60		
				te Porgenitor Cells," Thrombosis Re	search,
	EK	1994, Vol. 76, No. 1, pp.	33-45		
•		Sturm et al "Immunohis	tological Detection of Tissue Fa	ctor in Normal and Abnormal Human	Mommon
	EL			A Pathological Anatomy and Histopa	
		1992, 421:79-86	, , , , , , , , , , , , , , , , , , , ,	and motope	o.ogy,
		Toomey et al., "Localizat	tion of the Human Tissue Factor	Recognition Determinant of Human	Factor
	ЕМ	VIIa," The Journal of Bio	ological Chemistry, October 15,	1991, Vol. 266, No. 29, pp. 19198-19	9202
	EN	Tsao et al., "Monocytes (Can Be Induced by Lipopolysac	charide-Triggered T Lymphocytes To	Express
	LIV	Functional Factor VII/VI	la Protease Activity," J. Exp. Me	ed., April 1984, Vol. 159, pp. 1042-10)57
		Tsuda et al., "Developme	ent of Antitissue Factor Antibodie	es in Patients After Liver Surgery," B	lood, Vol.
	EO	82, No. 1 July 1, 1993, p			·
	EP	Walsh et al., "Discordant	Expression of Tissue Factor An	tigen and Procoagulant Activity on H nide," Thrombosis and Haemostasis	luman
	Er	(5), pp. 552-558	TI EF 3 and Low Dose Cyclonexii	nide, Thrombosis and Haemosiasis	, 1991, 66
			ed Intravascular Coagulation in F	Rabbits Induced by Administration of	Endotoxin
	EQ	or Tissue Factor: Effect	of Anti-Tissue Factor Antibodies	and Measurement of Plasma Extrin	sic Pathway
			Vol. 75, No. 7, April 1, 1990, pp		
				Activation of Protease-Activated Re	eceptor 2 by
	ER	Factor VIIa," PNAS, 97(1	0):5255-5260 (2000)		
	-	Ruf et al "Tissue Factor	Signaling "Thrombosis and Ha	emostasis, 82(2):175-182 (1999)	
	ES	Trail of al., Tissue Tactor	Olghamig, Thrombosis and Ha	emostasis, 62(2).173-162 (1999)	
				nelial Growth Factor Production by H	uman
	ET	Fibroblasts in Response	to Activated Factor VII," Blood,	91(8):2698-2703 (1998)	
		Miliagr et al. "Effects of [Pinding of Ligand (EV/IIa) to Indu	ced Tissue Factor in Human Endoth	olial Calle "
	EU	Thrombosis Research, 9		ced fissue Factor in Human Endoth	enai Cens,
			0.07. 02. (2000)		
				ance, Structure-Function Relationsh	ips and Its
	EV	Role in Signaling and Me	etastasis," Thrombosis Haemost	asis, 86:757-771 (2001)	

4 9				Sheet Page 6 c		
orm PTO-1449 INFORMATION DISCLOSURE CITATION		DISCLOSURE CITATION	Docket Number (Optional) TNA-005.04	Application Number 10/618,338		
	IN AN APPLICATION (Use several sheets if necessary)		Applicant	10/010,550		
			Jin-An Jiao et al.			
			Filing Date	Group Art Unit		
			July 11, 2003	1646		
		Riewald et al., "Mechan Factor," PNAS, 98(14):7		ling and Initiation of Coagulation by Tissue		
		1 43.01, 111.01, 30(14).1142 1141 (2001)				
		Mueller et al, "Expression	on of Tissue Factor by Melanoma	a Cells Promote Efficient Hematogenous		
			Acad. Sci. USA, 89:11832-1183			
	EY	Poster Presentation Exp Factor Antibodies	perimental Biology 2001, March	31-April 4, 2001, Orlando, Florida, Anti-Tissue		
	EZ		Antihemostatis Agents on Experostasis, 28(1):29-38 (2002)	rimental Tumor Dissemination," Sem. in		
	FA	Amirkhosravi et al., Suppl. to J. of Thrombosis and Haemostasis Abstract:OC1021 (2001)				